M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

Date: February 7, 2000

To: Dockets Management Branch (HFA-305)

From: Melissa Lamb
Office of Generic Drugs

Subject: Challenges Facing Generic Drug Approvals in the Next Millennium

This memorandum forwards overheads of a presentation to the Dockets Management Branch for inclusion in Docket 90S-0308. The following is information on the presentation for the Docket records:

Title of Presentation: Challenges Facing Generic Drug Approvals In the Next Millennium

Presented for: CBI Forum

Date Presented: 1/24/00

Presented by: Douglas L. Sporn

Number of Pages: 26

M. Lamb

Attachment

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90S-0308

M664

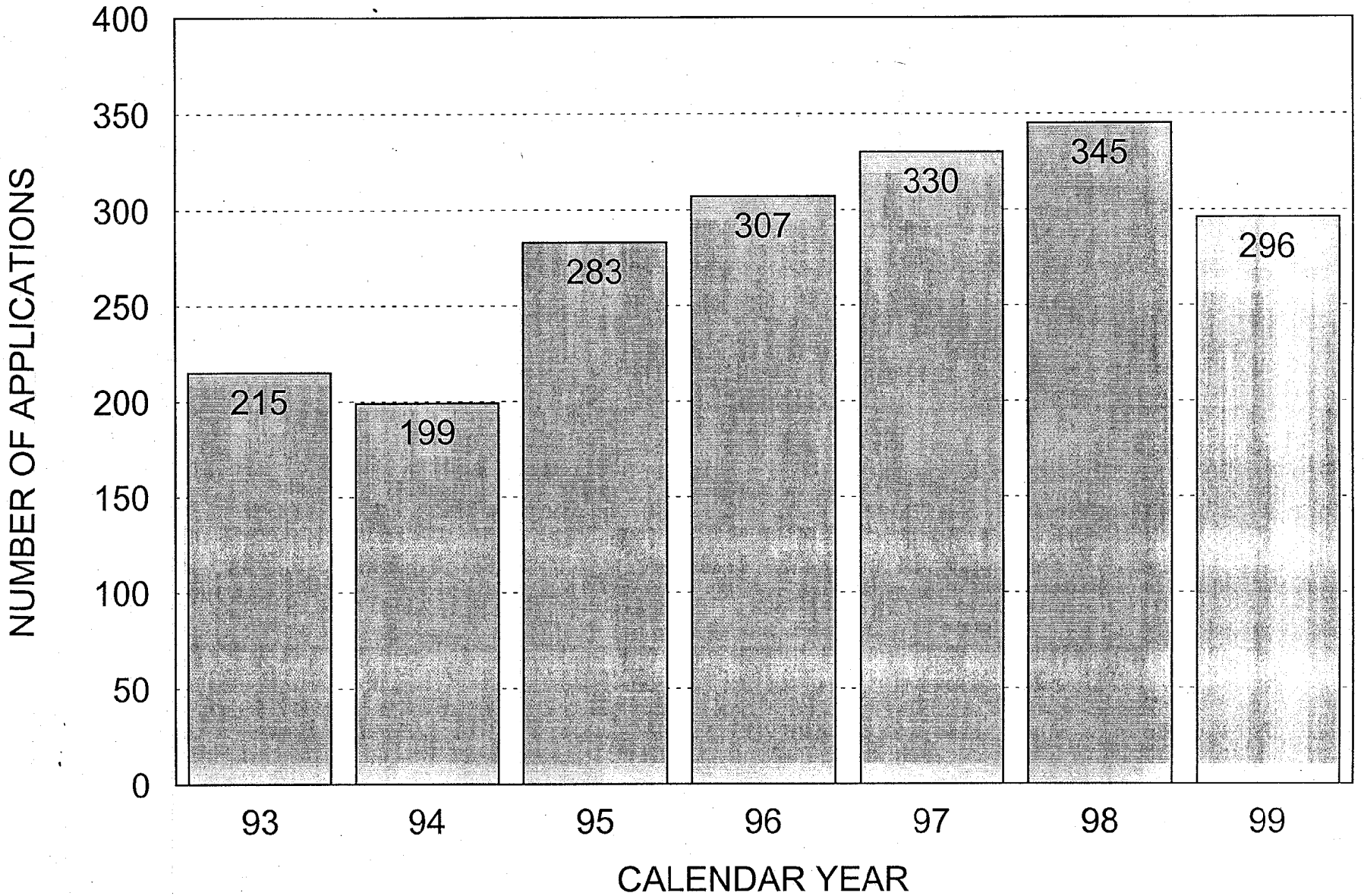
CBI Forum

Challenges Facing Generic Drug Approvals in the Next Millennium

Douglas L. Sporn, Director
Office of Generic Drugs
January 24, 2000
Washington, D.C.

- OGD Year End Review
- Challenges
  - Review Times
  - Staffing/Location Changes
  - Electronic Regulatory Submissions
  - Legal/Regulatory
  - Scientific Issues

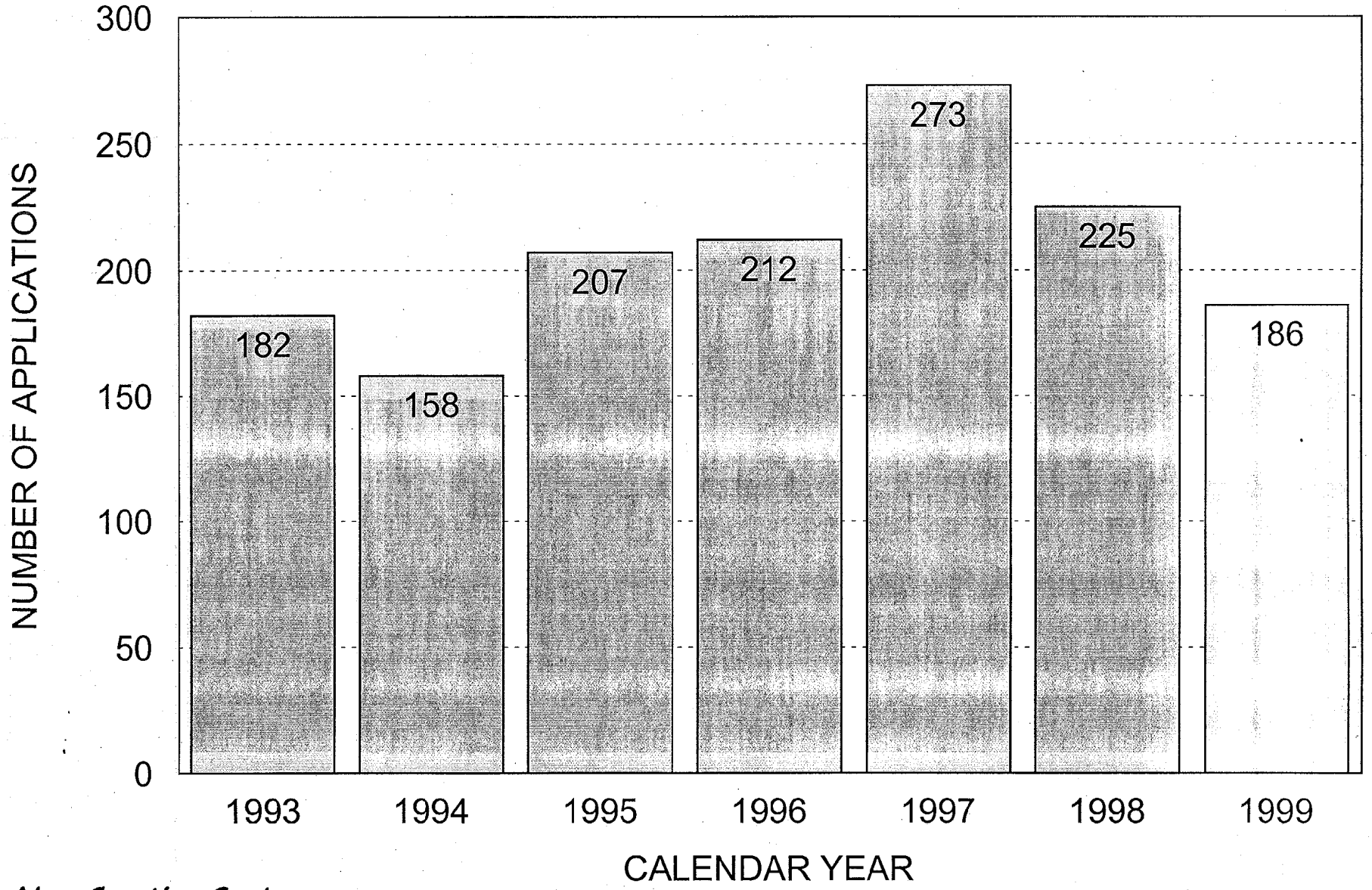
Calendar Year Receipts



New Counting System

December 31, 1999

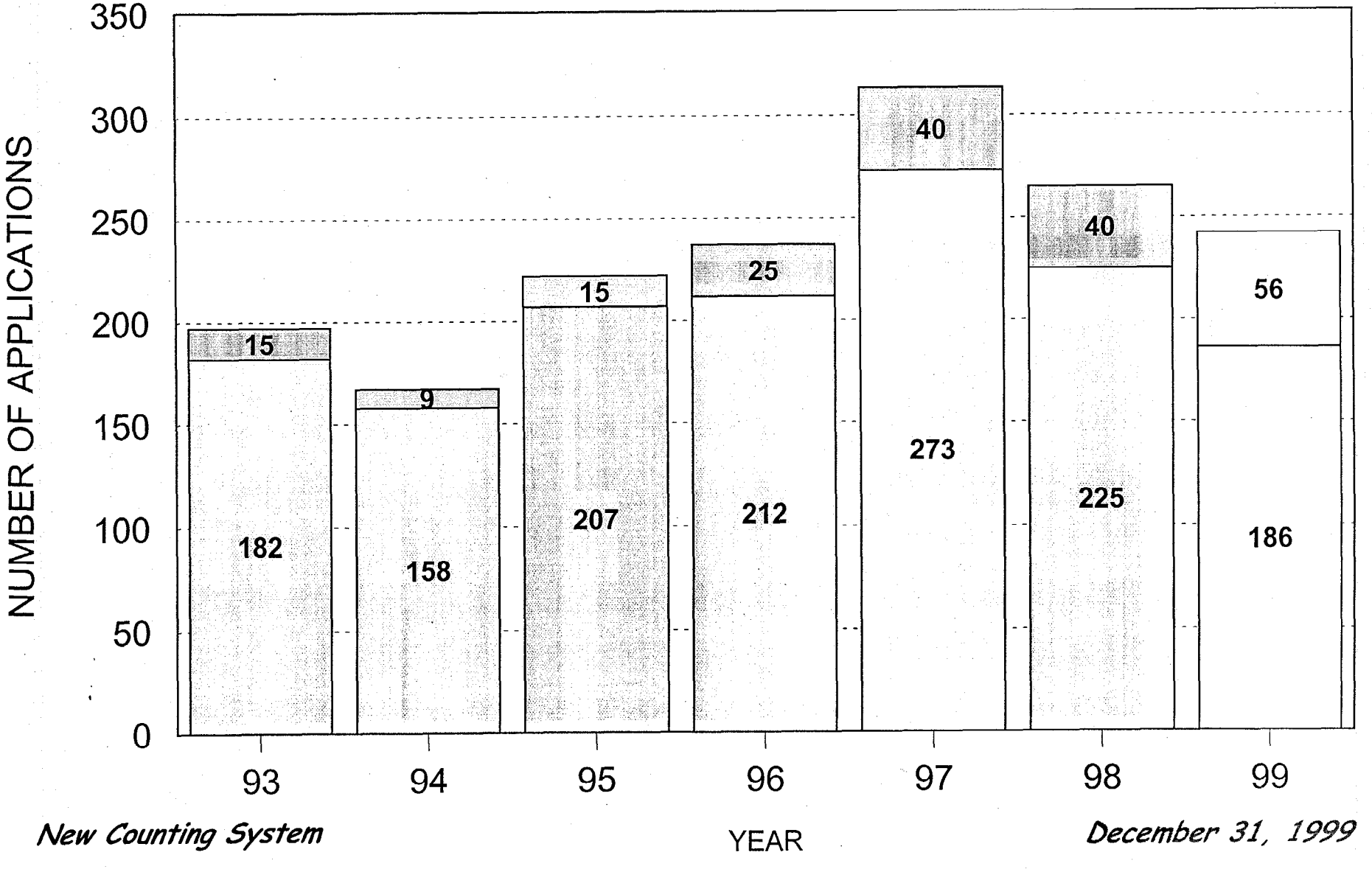
Calendar Year Approvals



New Counting System

December 31, 1999

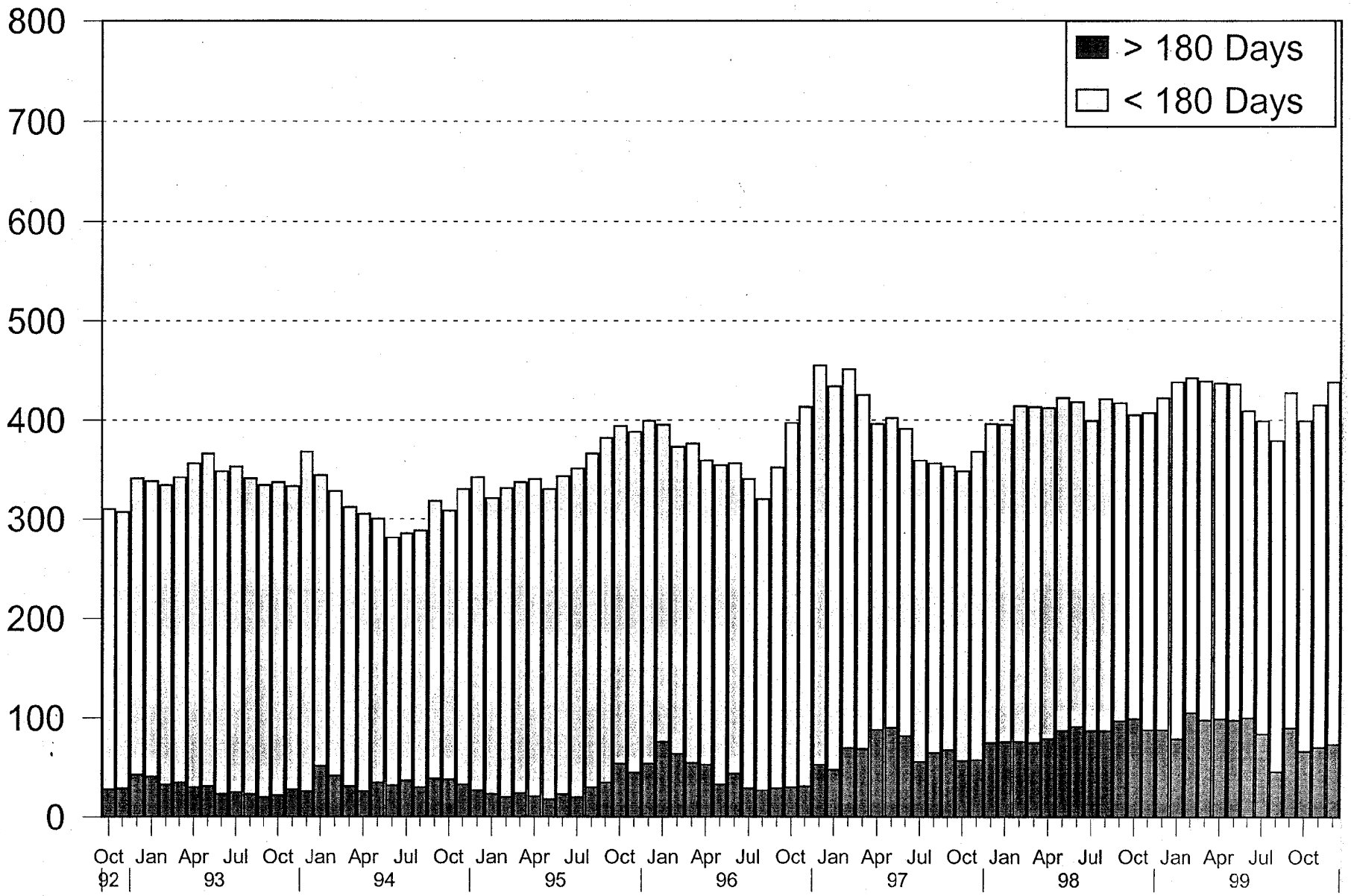
Calendar Year Approvals & Tentative Approvals



New Counting System

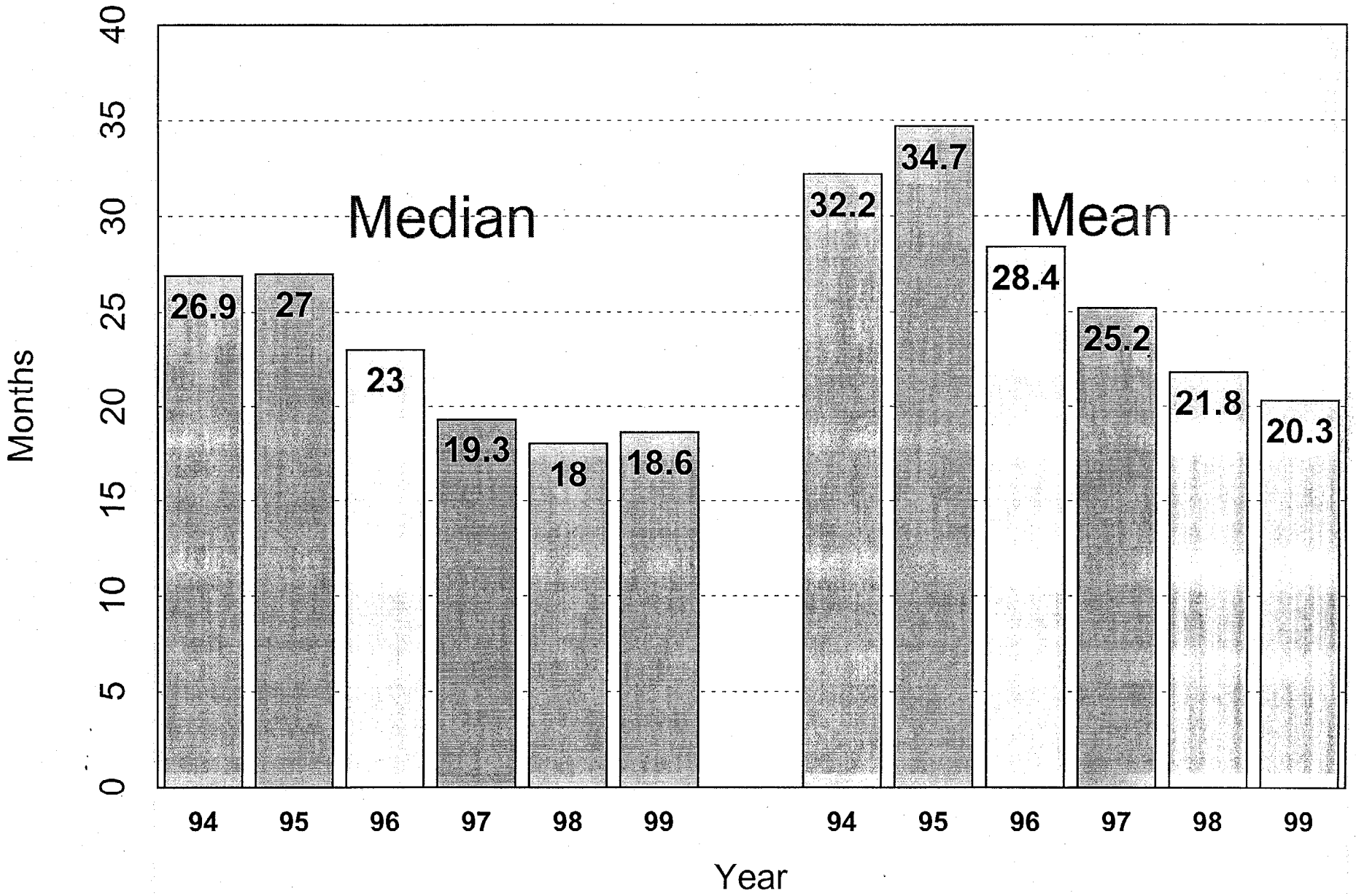
December 31, 1999

Original ANDAs Pending Per Month



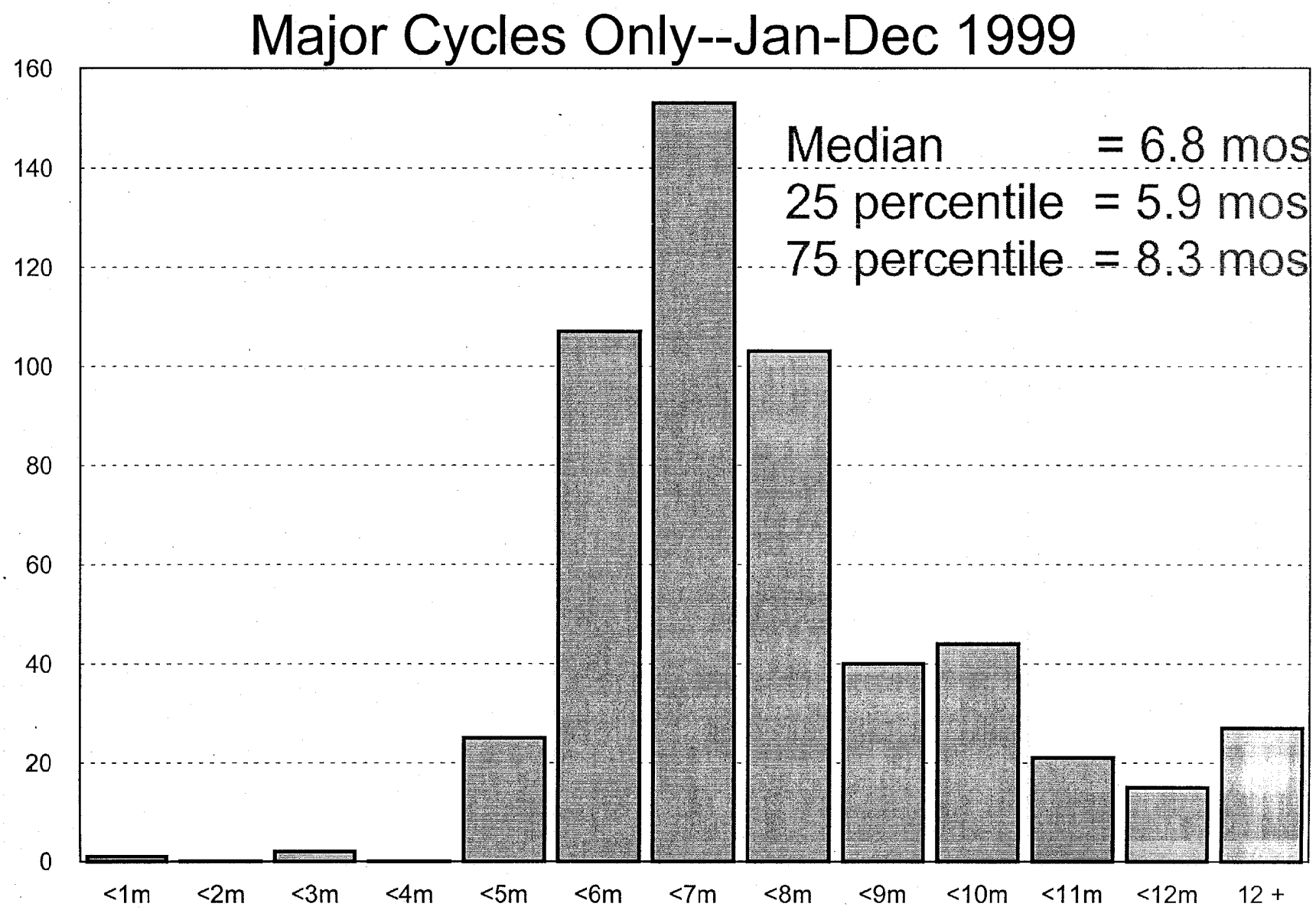
New Counting System

Calendar Year Approval Times



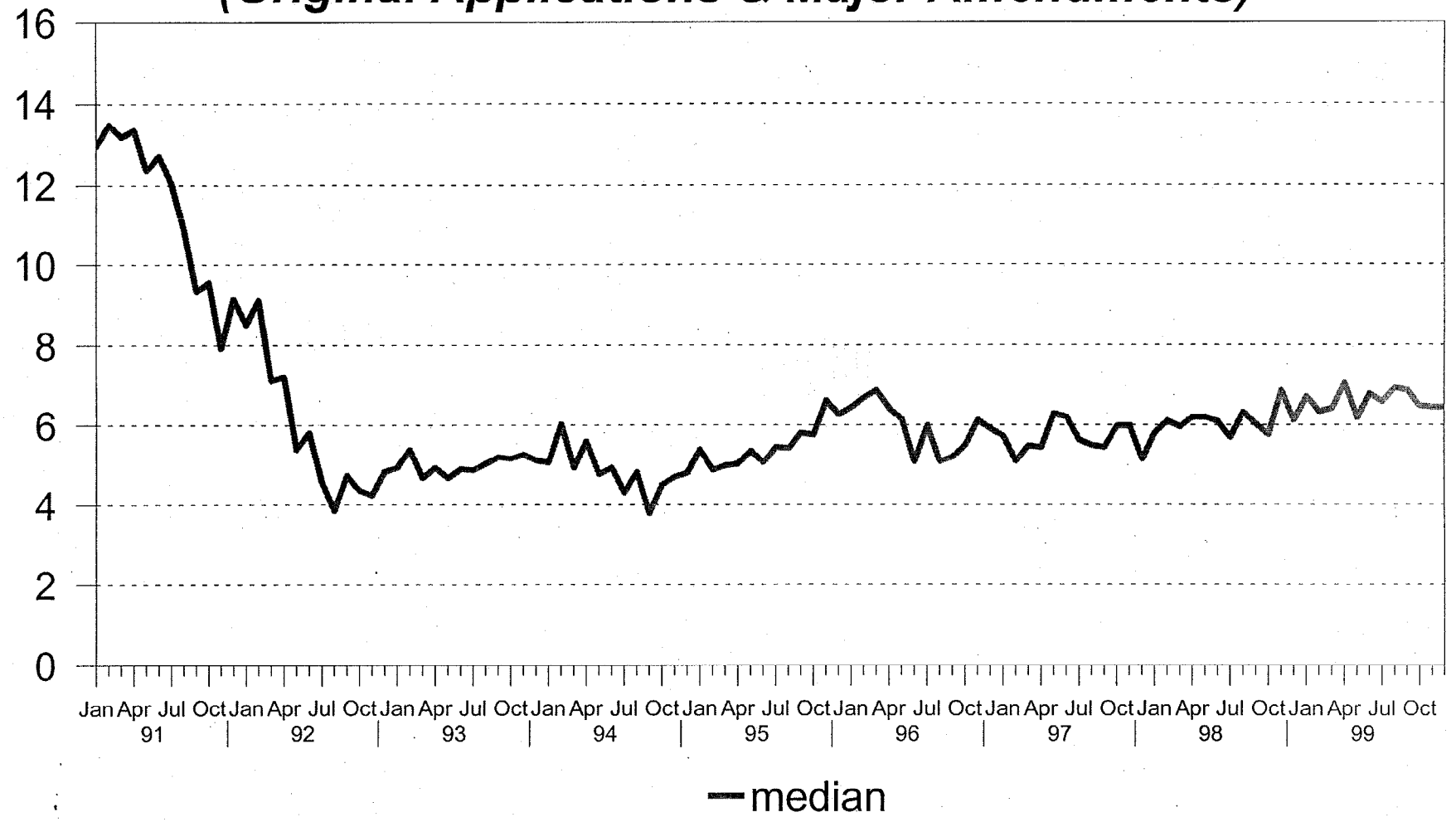
December 31, 1999

Distribution of Review Times for Original ANDAs



Median ANDA Review Cycle (Months)

(Original Applications & Major Amendments)



1-Times correspond to actual applications received . The new ANDA/AADA submission policy that went into effect 1/1/91 allows certain variations in a drug product to be included in a single application.

2-In September, 1991 the OGD started implementation of the Application Integrity Policy by suspending review of applications suspected of being tainted by fraud. AIP time has been subtracted from review time above for the period after 9/91. However, before the AIP went into effect, the review of many applications suspected of containing fraudulent data were suspended. These suspensions were not recorded in the MIS and are not reflected in the above chart.

Staffing/Location Changes

OGD Personnel by Discipline

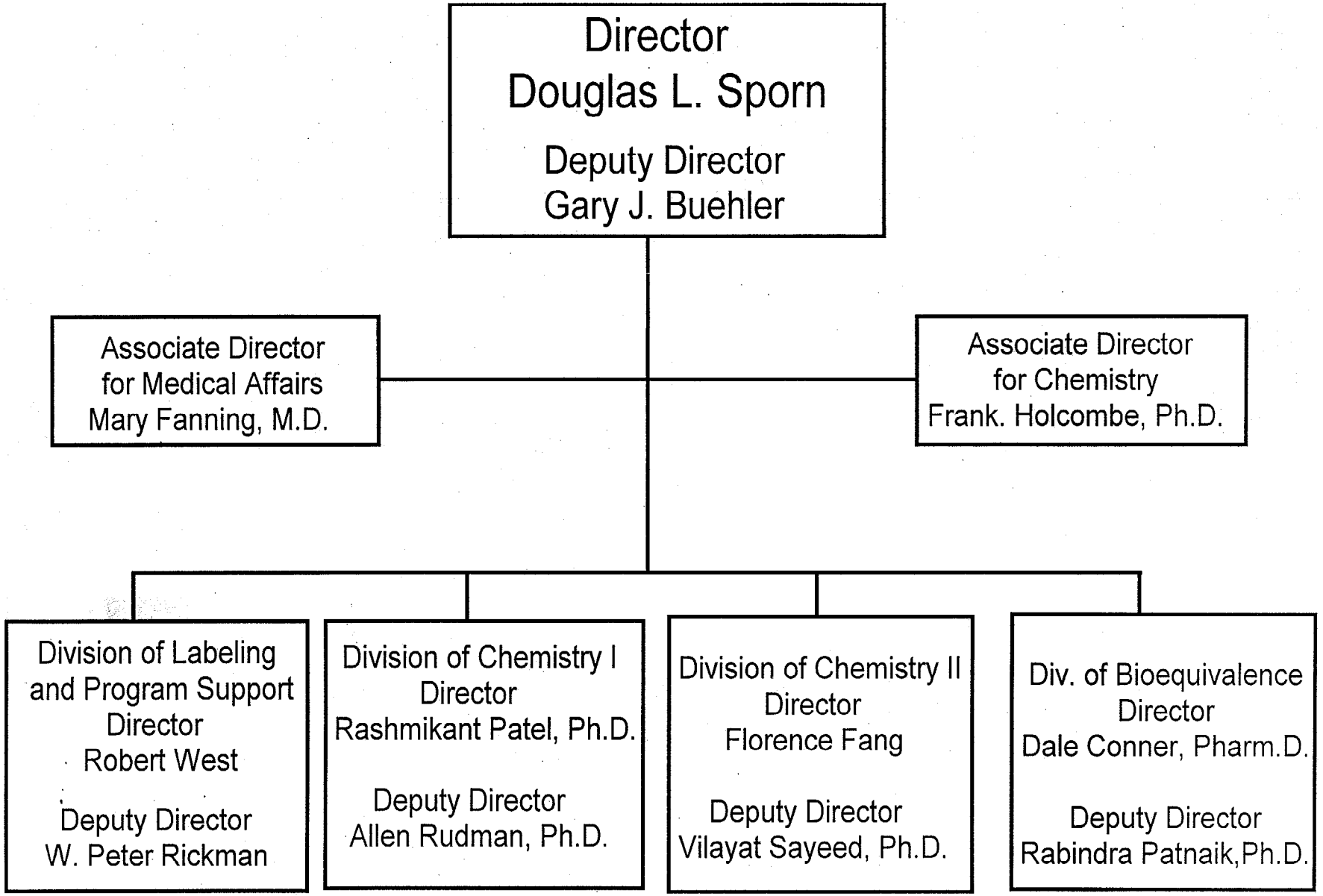
	FY 99 Ceiling	Change
Chemistry Reviewers	49	+2
Bioequivalence Reviewers	26	+1
Project Managers/Technician	15	+4
Clerical	9	+2
Labeling Reviewers	11	+1
Management/Admin. Support	9	
Microbiologists	4	+1
Application Examiners	2	
Medical Officer	1	
Computer Specialist	2	
Statistician	1	
Total	129	140

- Relatively New Staff
  - Micro Reviewers: 75% ≤ 1 Yr
  - Chemistry Reviewers: 20% ≤ 1 Yr
  - Project Managers: 50% ≤ 1 Yr

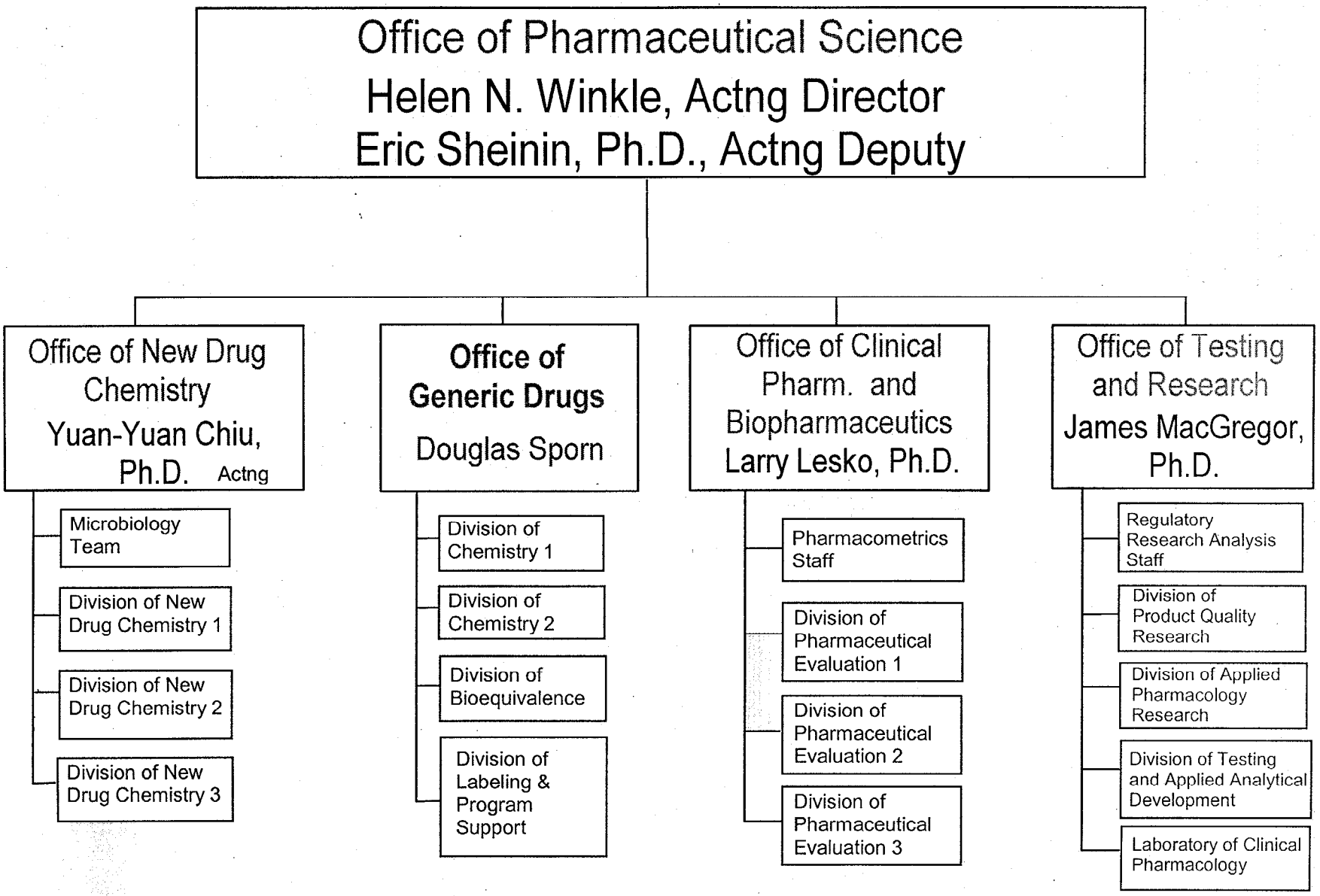
Leadership Changes

- New Office of Pharmaceutical Science Director
- New Office of Generic Drugs Director

Office of Generic Drugs



Center for Drug Evaluation and Research



Location Changes

2002 - Some CDER Offices relocate to:

Site of former Naval Surface Warfare Center - White Oak

Silver Spring, MD

Electronic Regulatory Submission & Review (ERSR)

- Currently accepting bioequivalence & CMC data submissions
- Achieve format of paperless archive - PDF and data files
  All components of an ANDA by FY2000
- By end of FY 2002, DMFs, annual reports, registration

Legal

- Lawsuits
- Citizen Petitions

Pending Citizen Petitions & Lawsuits

Number of Pending Petitions Needing OGD Input	22	(14)
Number of Lawsuits Involving OGD	7	(5)

Active Citizen Petitions and Lawsuits

Topic	Petitions	Lawsuit
Amiodarone	✔	
Cyclosporine		✔
Diltiazem	✔	
DPK	✔✔✔✔	
Enalapril	✔	
Estradiol TDS	✔	
Nifedipine		✔

Active Citizen Petitions and Lawsuits

Topic	Petitions	Lawsuit
P. IV Internet	✔	
Parenteral Drugs	✔	
Phenytoin		✔
Propafenone	✔	
Propofol	✔✔	✔
Suitability Petition	✔	
Terazosin		✔

Regulatory/Legislative

- Proposed 180-Day Exclusivity Regulation
- State Legislative Efforts: NTI Drugs

180-Day Generic Drug Exclusivity

- August 6, 1999 - Proposed Rule Published
- November 4, 1999 - Comment Period Closed
- Number of Commentors - 18

Why a Proposal?

- Previous regulation was successfully challenged in the courts
  - *Mova Pharmaceutical Corp v. Shalala, 1998*
  - *Granutec, Inc. v. Shalala, 1998*

- New Wrinkle...
  - *Mylan v. FDA, 2000*

Scientific/Pharmaceutical Use Issues

- Post-Marketing Strategies
- Guidance Development
- Variations in Reference Listed Drugs